

II. FY 01: BPD Reports Submitted By Blood And Plasma Establishments:

Total BPDs By Manufacturing System

MANUFACTURING SYSTEM	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
POST DONATION INFORMATION	14698	126	0	3497	18321	73.4%
QC & DISTRIBUTION	1553	378	210	100	2241	9.0%
LABELING	903	330	152	14	1399	5.6%
DONOR SCREENING	1031	29	0	201	1261	5.1%
MISCELLANEOUS	384	38	30	159	611	2.4%
ROUTINE TESTING	316	108	117	2	543	2.2%
COMPONENT PREPARATION	237	20	9	0	266	1.1%
BLOOD COLLECTION	142	4	0	8	154	0.6%
DONOR DEFERRAL	66	1	0	23	90	0.4%
VIRAL TESTING	68	5	1	9	83	0.3%
<i>TOTAL</i>	<i>19398</i>	<i>1039</i>	<i>519</i>	<i>4013</i>	<i>24969</i>	<i>100%</i>

Reportable BPDs By Manufacturing System

MANUFACTURING SYSTEM	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
POST DONATION INFORMATION	14636	126	0	3494	18256	76.6%
QC & DISTRIBUTION	1229	365	200	98	1892	7.9%
LABELING	833	321	149	10	1313	5.5%
DONOR SCREENING	997	24	0	189	1210	5.1%
ROUTINE TESTING	315	108	117	2	542	2.3%
COMPONENT PREPARATION	235	20	9	0	264	1.1%
BLOOD COLLECTION	139	4	0	7	150	0.6%
DONOR DEFERRAL	66	1	0	23	90	0.4%
VIRAL TESTING	68	5	1	8	82	0.3%
MISCELLANEOUS	36	2	0	2	40	0.2%
<i>TOTAL</i>	<i>18554</i>	<i>976</i>	<i>476</i>	<i>3833</i>	<i>23839</i>	<i>100%</i>

Potential Recalls By Manufacturing System

MANUFACTURING SYSTEM	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
DONOR SCREENING	692	9	0	122	823	49.3%
QC & DISTRIBUTION	190	6	0	75	271	16.2%
COMPONENT PREPARATION	151	3	0	0	154	9.2%
LABELING	127	3	0	8	138	8.3%
POST DONATION INFORMATION	92	0	0	13	105	6.3%
BLOOD COLLECTION	78	0	0	5	83	5.0%
DONOR DEFERRAL	47	1	0	18	66	4.0%
VIRAL TESTING	20	0	0	1	21	1.3%
ROUTINE TESTING	9	0	0	0	9	0.5%
TOTAL	1406	22	0	242	1670	100%

Most Frequent Types of Reportable PDI From Licensed Blood Establishments

POST DONATION INFORMATION (PDI)	# Reports	% of Total PDI
<i>Behavior/History</i>	13427	91.7%
Travel to malaria endemic area/history of malaria	3724	25.4%
Risk factors associated with Creutzfeldt-Jakob Disease - lived in United Kingdom (nvCJD)	2777	19.0%
History of cancer	1112	7.6%
History of disease	623	4.3%
Donor received tattoo within 12 months of donation	584	4.0%
Received medication or antibiotics	428	2.9%
IV drug use	393	2.7%
Male donor had sex with another man	364	2.5%
History of jaundice	302	2.1%
Sex partner tested positive for HCV	301	2.1%
Received Proscar, Tegison or Accutane	247	1.7%
<i>Illness</i>	894	6.1%
Post donation illness (not hepatitis, HIV, HTLV-I, STD, or cold/flu related)	869	5.9%
<i>Testing *</i>	220	1.5%

*Includes: tested positive for viral marker either prior to or post donation

Most Frequent Types Of Reportable Quality Control & Distribution BPDs From Licensed Blood Establishments

QC & DISTRIBUTION	# Reports	% of Total QC & Distribution
<i>Unsuitable product</i>	631	51.3%
Unit or segments contained clots or would not flow through filter	457	37.2%
Unit or segment hemolyzed	162	13.2%
<i>Failure to quarantine unit due to:</i>	214	17.4%
Product QC unacceptable or not documented (describe)	76	6.2%
Unit released prior to resolution of discrepancy	30	2.4%
Outdated product	23	1.9%
Instrument QC or validation unacceptable or not documented	20	1.6%
<i>Shipping and storage</i>	186	15.1%
Shipped at incorrect temperature	156	12.7%
Stored at incorrect temperature	27	2.2%
<i>Failure to quarantine unit due to medical history:</i>	60	4.9%
Other (e.g., post donation information or illness)	27	2.2%
<i>Improper blood bank practices</i>	58	4.7%
<i>Failure to quarantine unit due to incorrect, incomplete, or positive testing</i>	52	4.2%
<i>Failure to quarantine unit due to testing not performed or documented</i>	27	2.2%

Most Frequent Types Of Reportable Donor Screening BPDs From Licensed Blood Establishments

DONOR SCREENING	# Reports	% of Total Donor Screening
<i>Donor gave history which warranted deferral and was not deferred</i>	636	63.8%
Travel to malaria endemic area/history of malaria	318	31.9%
Received medication or antibiotics	79	7.9%
History of cancer	56	5.6%
History of disease	44	4.4%
History of jaundice	34	3.4%
<i>Donor record incomplete, incorrect, or not reviewed</i>	187	18.8%
Donor history questions	118	11.8%
Arm inspection	28	2.8%
<i>Incorrect ID used during deferral search</i>	100	10.0%
<i>Donor not previously deferred</i>	60	6.0%
<i>Donor previously deferred due to testing</i>	27	2.7%
<i>Donor did not meet acceptance criteria</i>	51	5.1%
Hemoglobin or Hematocrit unacceptable or not documented	29	2.9%
Temperature unacceptable or not documented	20	2.0%
<i>Deferral screening not done</i>	23	2.3%

**Most Frequent Types of Reportable Labeling BPDs
From Licensed Blood Establishments**

LABELING	# Reports	% of Total Labeling
<i>Missing/incorrect label or tag</i>	535	64.2%
Autologous information	189	22.7%
Recipient number or name	56	6.7%
Donor number	50	6.0%
Biohazard or test status	43	5.2%
Volume	40	4.8%
Leukoreduced	30	3.6%
Irradiation	29	3.5%
<i>Blood unit labels</i>	298	35.8%
Extended expiration date	124	14.9%
ABO and/or Rh incorrect	59	7.1%
Product type incorrect	36	4.3%

**Most Frequent Types of Reportable Quality Control & Distribution BPDs From
Unlicensed Blood Establishments**

QC & Distribution	# Reports	% of Total QC & Distribution
<i>Improper blood bank practices</i>	194	53.2%
Product not irradiated as required	63	17.3%
Other*	34	9.3%
Product not leukoreduced as required	32	8.8%
Improper ABO or Rh type selected for patient	25	6.8%
Unit issued to wrong patient	21	5.8%
Improper product selected for patient	19	5.2%
<i>Failure to quarantine unit due to testing not performed or documented for:</i>	64	17.5%
Other (e.g., crossmatch, multiple tests, recheck of ABO or Rh)	27	7.4%
Antigen screen	14	3.8%
ABO	13	3.6%
Antibody screen	10	2.7%
<i>Unsuitable product</i>	42	11.5%
Unit or segments contained clots or would not flow through filter	40	11.0%
<i>Failure to quarantine unit due to:</i>	27	7.4%
Outdated product	11	3.0%
Instrument QC or validation unacceptable or not documented	8	2.2%
<i>Shipping and storage</i>	21	5.8%
Stored at incorrect temperature	10	2.7%
Shipped at incorrect temperature	10	2.7%
<i>Failure to quarantine due to incorrect, incomplete, or positive testing:</i>	15	4.1%

* Includes product not CMV or Hgb S negative as required; multiple special requirements not met; unit released without computer documentation-visual inspection not documented

**Most Frequent Types of Reportable Labeling BPDs From
Unlicensed Blood Establishments**

LABELING	# Reports	% of Total Labeling
<i>Missing/incorrect label or tag</i>	<i>173</i>	<i>53.9%</i>
Recipient number or name	59	18.4%
Donor number	52	16.2%
Other (multiple labels, unit Rh, patient ABO, pool number)	12	3.7%
Crossmatch	12	3.7%
Irradiation	10	3.1%
Leukoreduced	8	2.5%
<i>Blood unit labels</i>	<i>148</i>	<i>46.1%</i>
Extended expiration date	77	24.0%
ABO and/or Rh incorrect	29	9.0%
Donor number incorrect or missing	13	4.0%
Product type incorrect	12	3.7%

**Most Frequent Types Of Post Donation Information (PDI)
From Unlicensed Blood Establishments**

POST DONATION INFORMATION (PDI)	# Reports	% of Total PDI
<i>Behavior/History</i>	<i>112</i>	<i>88.9%</i>
Travel to malaria endemic area/history of malaria	38	30.2%
Risk factors associated with Creutzfeldt-Jakob Disease - lived in United Kingdom (nvCJD)	30	23.8%
Donor received bone graft or transplant within 12 months of donation	5	4.0%
Sex partner tested positive for HCV	4	3.2%
Sex partner lived in or immigrated from an HIV Group O risk area	4	3.2%
Donor received tattoo within 12 months of donation	4	3.2%
History of cancer	4	3.2%
History of disease	3	2.4%
Received Proscar, Tegison or Accutane	3	2.4%
Sex partner engaged in high risk behavior	2	1.6%
Donor received ear piercing within 12 months of donation	2	1.6%
<i>Illness</i>	<i>13</i>	<i>10.3%</i>

Most Frequent Types of Reportable Routine Testing BPDs From Unlicensed Blood Establishments

ROUTINE TESTING	# Reports	% of Total Routine Testing
<i>Incorrectly tested for:</i>	85	78.7%
Compatibility	39	36.1%
Antibody screening	25	23.1%
ABO	8	7.4%
Antigen typing	6	5.6%
Rh	5	4.6%
<i>Sample identification</i>	23	21.3%
Sample (<i>used for testing</i>) misidentified	15	13.9%
Incorrect sample tested	8	7.4%

Most Frequent Types of Reportable Quality Control & Distribution BPDs From Transfusion Services

QC & DISTRIBUTION	# Reports	% of Total QC & Distribution
<i>Improper blood bank practices</i>	104	52.0%
Product not leukoreduced as required	26	13.0%
Product not irradiated as required	23	11.5%
Improper ABO or Rh type selected for patient	22	11.0%
Other*	13	6.5%
Improper product selected for patient	12	6.0%
Unit issued from the blood bank to wrong patient	8	4.0%
<i>Failure to quarantine unit due to testing not performed or documented for:</i>	44	22.0%
Antibody screen	14	7.0%
Other (e.g., multiple tests; crossmatch; Hgb S)	13	6.5%
Antigen screen	12	6.0%
Rh	3	1.5%
ABO	2	1.0%
<i>Shipping and/or storage temperature incorrect</i>	20	10.0%
<i>Failure to quarantine unit due to:</i>	17	8.5%
Outdated product	14	7.0%
Other (e.g., previous positive antibody screen; inspection not documented)	3	1.5%
<i>Failure to quarantine unit due to incorrect, incomplete, or positive testing for:</i>	8	4.0%
Antigen screen	4	2.0%
Other (e.g., crossmatch)	2	1.0%
Anti-HBc	1	0.5%
Antibody screen	1	0.5%
<i>Unsuitable product:</i> unit or segments contained clots or would not flow through filter-visual inspection not performed or documented, unit returned	7	3.5%

* Includes product not CMV negative as required; multiple special requirements not met; incorrect filter issued; inappropriate reissue of returned product

**Most Frequent Types of Reportable Labeling BPDs
Received From Transfusion Services**

LABELING	# Reports	% of Total Labeling
<i>Missing/incorrect label or tag</i>	96	64.4%
Recipient number or name	44	29.5%
Donor number	33	22.1%
Other (unit Rh, RBC tag attached to FFP, patient ABO, multiple labels)	8	5.4%
Volume	3	2.0%
CMV	2	1.3%
Crossmatch	2	1.3%
Leukoreduced	2	1.3%
Antigen	1	0.7%
HLA	1	0.7%
<i>Blood unit labels</i>	53	35.6%
Extended expiration date	26	17.4%
ABO and/or Rh incorrect	9	6.0%
Donor number incorrect or missing	7	4.7%
Product type incorrect	5	3.4%
Missing expiration date	2	1.3%
Multiple labels missing or incorrect (describe)	2	1.3%
Other (e.g., lab number not assigned)	1	0.7%
ABO and/or Rh missing	1	0.7%

**Most Frequent Types of Reportable Routine Testing BPDs
From Transfusion Services**

ROUTINE TESTING	# Reports	% of Total Routine Testing
<i>Incorrectly tested for:</i>	83	70.9%
Compatibility	27	23.1%
Antibody screening	26	22.2%
Rh	14	12.0%
Antigen typing	8	6.8%
<i>Sample (used for testing) identification</i>	34	29.1%
Sample misidentified	28	23.9%
Incorrect sample tested	6	5.1%

Most Frequent Types of Reportable PDI From Plasma Centers

POST DONATION INFORMATION (PDI)	# Reports	% of Total PDI
<i>Behavior/History</i>	3402	97.4%
Donor received tattoo within 12 months of donation	1075	30.8%
Donor received body piercing within 12 months of donation	587	16.8%
Incarcerated	423	12.1%
Other (e.g., unknown; deferred by another center; positive drug screen)	290	8.3%
IV drug use	104	3.0%
Non-IV-drug use	98	2.8%
Donor received ear piercing within 12 months of donation	79	2.3%
Donor had multiple blood or body fluid exposures, e.g., tattoo and piercing (describe)	72	2.1%
Risk factors associated with Creutzfeldt-Jakob Disease - lived in United Kingdom (nvCJD)	72	2.1%
Sex partner tested positive for HIV	71	2.0%
Male donor had sex with another man	56	1.6%
History of disease	52	1.5%
Sex partner tested positive for HCV	51	1.5%
<i>Testing*</i>	83	2.4%
Other (e.g., deferred by another center-testing not specified; ALT)	61	1.7%

*Includes testing positive for viral marker prior to or post donation

Most Frequent Types of Reportable Donor Screening BPDs Received From Plasma Centers

DONOR SCREENING	# Reports	% of Total Donor Screening
<i>Donor record incomplete, incorrect, or not reviewed</i>	60	31.7%
Donor history questions	38	20.1%
Arm inspection	13	6.9%
Donor identification	7	3.7%
<i>Deferral screening not done</i>	54	28.6%
<i>Donor previously deferred due to history</i>	33	17.5%
Incarcerated	7	3.7%
IV drug use	6	3.2%
Other (e.g., positive drug screen; unknown)	5	2.6%
<i>Donor previously deferred due to testing:</i>	21	11.1%
Other (e.g., unknown; deferred by another center)	7	3.7%
Elevated for ALT	6	3.2%
Reactive for Anti-HCV	4	2.1%
<i>Donor gave history which warranted deferral and was not deferred</i>	35	18.5%
Other (e.g., unable to read; no permanent address)	7	3.7%
Donor received body piercing within 12 months of donation	5	2.6%
Non-IV-drug use	4	2.1%
<i>Donor did not meet acceptance criteria</i>	31	16.4%
Medical review or physical not performed or inadequate	17	9.0%
Temperature unacceptable or not documented	9	4.8%
Unexplained weight loss	5	2.6%
<i>Incorrect ID used during deferral search</i>	8	4.2%
<i>Donor previously deferred due to history</i>	6	3.2%

Non-Reportable Events By Manufacturing System

MANUFACTURING SYSTEM	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
MISCELLANEOUS	348	36	30	157	571	50.5%
QC & DISTRIBUTION	324	13	10	2	349	30.9%
LABELING	70	9	3	4	86	7.6%
POST DONATION INFORMATION	62	0	0	3	65	5.8%
DONOR SCREENING	34	5	0	12	51	4.5%
BLOOD COLLECTION	3	0	0	1	4	0.4%
COMPONENT PREPARATION	2	0	0	0	2	0.2%
ROUTINE TESTING	1	0	0	0	1	0.1%
VIRAL TESTING	0	0	0	1	1	0.1%
TOTAL	844	63	43	180	1130	100%

Most Frequent Types of Non-Reportable Miscellaneous Events

MISCELLANEOUS	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
Product made available for distribution, but not distributed	175	42.3%	107	68.2%	282	49.1%
No products made available for distribution	78	18.8%	15	9.6%	93	16.2%
Minor recordkeeping deviation (testing and labeling are acceptable)	37	8.9%	16	10.2%	53	9.2%
Product determined to be suitable prior to distribution	42	10.1%	9	5.7%	51	8.9%
Notification/retrieval procedures not followed	27	6.5%	3	1.9%	30	5.2%
Product not under control of reporting establishment when deviation occurred	18	4.3%	0	0.0%	18	3.1%
Emergency released unit not tested prior to release and found positive, labeled appropriately	13	3.1%	0	0.0%	13	2.3%

Most Frequent Types of Non-Reportable Quality Control & Distribution Events

QC & DISTRIBUTION	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
Product broken or was damaged and product was discarded	247	71.2%		0.0%	247	70.8%
QC not performed or inadequate (other than viral marker, ABO/Rh)	67	19.3%	1	50.0%	68	19.5%

Most Frequent Types of Non-Reportable Labeling Events

LABELING	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
Unlicensed unit labeled with license number	48	58.5%	0	0.0%	48	55.8%
Unit labeled with shortened expiration date	20	24.4%	3	75.0%	23	26.7%
Unit labeled with missing/incorrect facility identifiers; unit acceptable	9	11.0%	1	25.0%	10	11.6%

BLOOD AND PLASMA

Timeliness Of Reportable BPDs

Number of Days From Date Discovered To Date FDA Received

CUMULATIVE % OF REPORTS	Licensed (Days)	Unlicensed (Days)	Transfusion Service (Days)	Plasma (Days)	Total (Days)
10%	15	8	7	20	15
25%	21	14	15	30	22
50%	30	27	29	45	31
75%	41	41	43	74	45
90%	63	50	54	150	77
# REPORTS	18506	974	475	3826	23781
RANGE	0-1044	0-377	0-284	3-1099	1-1099
AVERAGE	41	31	32	75	46
# Reports lacking date discovered	48	2	1	7	58

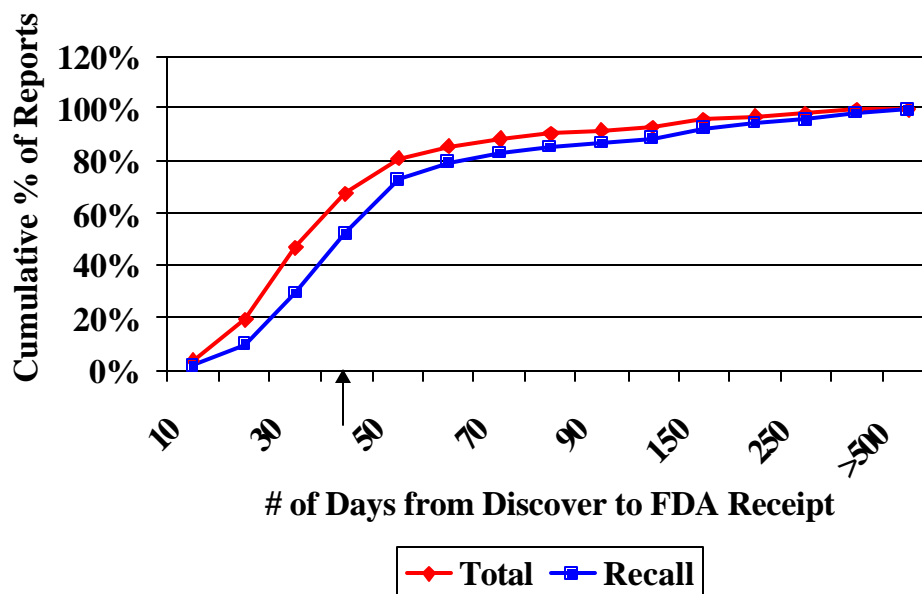
Adherence To 45 Day Required Timeframe For Reporting

(Reporting Time = Date of FDA receipt – Date of Discovery of BPD)

Reporting Time (days)	Licensed Establishments		Unlicensed Establishments		Transfusion Services		Plasma Centers		Total	
< or = 45 *	14746	79.7%	808	83.0%	385	81.1%	1890	49.4%	17829	75.0%
Between 45 and 90	2612	14.1%	140	14.4%	82	17.3%	1213	31.7%	4047	17.0%
> 90	1148	6.2%	26	2.7%	8	1.7%	723	18.9%	1905	8.0%
Total	18506	100%	974	100%	475	100%	3826	100%	23781	100%

*Reporting time for 10 reports = 0; they were submitted electronically on the day discovered.

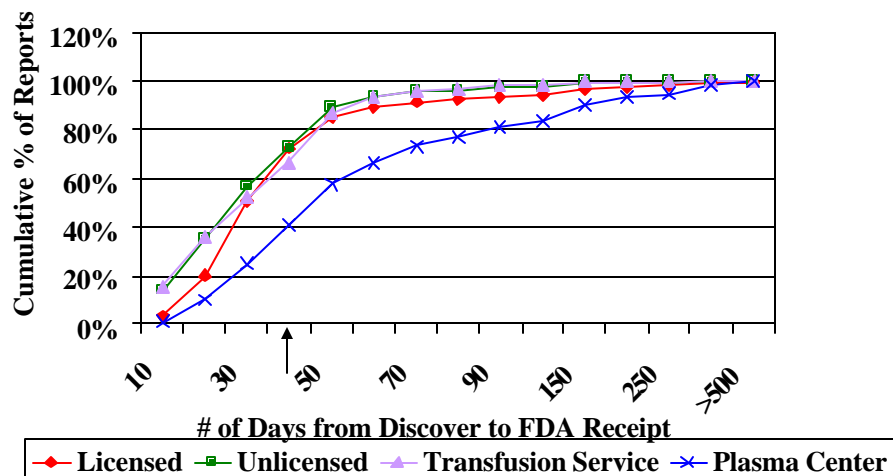
FY-2001 Blood and Plasma BPD Reporting Timeliness



Total Reports = 23,781

Potential Recalls = 1670

FY-2001 Reporting Time Total Reports

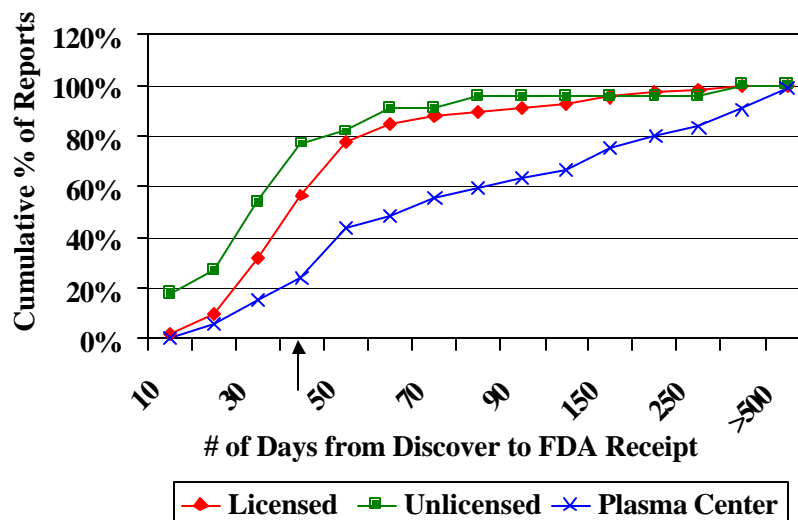


Total Reports = 23,781

Licensed Blood Est. = 18,506; Unlicensed Blood Est. = 974; Transfusion Services = 475;

Plasma Centers = 3826

FY-2001 Reporting Time Potential Recalls



Total Reports = 1670

Licensed Blood Est. = 1406; Unlicensed Blood Est. = 22; Plasma Centers = 242